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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------|
| 10/037,236 | 11/09/2001 | James F. Zucherman | KLYC-01056US8 SRM/SDS | 6669 |
| 23910 | 7590 | 01/06/2006 | EXAMINER | |
| FLIESLER MEYER, LLP FOUR EMBARCADERO CENTER SUITE 400 SAN FRANCISCO, CA 94111 | | | REIP, DAVID OWEN | |
| | | ART UNIT | PAPER NUMBER | 3733 |

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/037,236 | ZUCHERMAN ET AL. |
| | Examiner David O. Reip | Art Unit 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 October 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 60-67,97,106 and 108-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 60-66,97,106,108-110 and 112-118 is/are rejected.
- 7) Claim(s) 67 and 111 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 60, 61, 109, 112, and 114-116 are rejected under 35 U.S.C. 102(b) as being anticipated by Voydeville Gilles (FR 2724554) (hereafter “Voydeville”). Figs. 1-4 of Voydeville show an implant for placing between spinous processes, the implant having all the limitations as recited in the above listed claims, including: a “body” comprising the combination of elements 5 and 6; a “shaft” 2; a compressible cylindrical spacer 1 rotatably mounted on the “shaft” 2; a first “wing” 3; and a second “wing” 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 62-66, 97, 106, 108, 110, 113, 117, and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voydeville. As previously discussed, Voydeville shows a device that is basically the same as that recited in the above listed claims. However, Voydeville does not show the spacer having alternative shapes of elliptical, oval, and egg-shaped. Further, although Voydeville discloses that the spacer 1 is made of a "semi-rigid" material, the reference is silent as to the specific material of construction. It would have been obvious to one of ordinary skill in the art at the time

the invention was made to construct the spacer to have any anatomically compatible cross-sectional shape, including elliptical, oval, and egg-shaped as claimed, and further to select any biocompatible, semi-rigid material as a suitable material of construction, including silicone, high molecular weight polymer, thermoplastic elastomer, or polycarbonate urethane as claimed.

Allowable Subject Matter

Claims 67 and 111 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive. First, the spacer 6 as seen in the Voydeville '634 U.S. patent is clearly not the same as the cylindrical spacer 1 as seen in the Voydeville '554 French patent. It is agreed that the '634 U.S. patent shows that the spacer 6 comprises two pairs of throughbores or "ducts" 7 and 8 for the passage of the artificial ligaments. However, it is clear that the '554 French patent shows a different spacer than that of the '634 U.S. patent, comprising a cylindrical spacer 1 with a single, axial throughbore (see the English abstract attached to the '554 French patent that describes "A cylindrical or similar shock-absorbing component (1) is located between two adjacent vertebral projections (E1,E2) to receive artificial ligaments which pass through *its central*

aperture" (italics emphasis added). Therefore, such a structure provides the inherent capability for the spacer to be able to be rotated about either or both "shafts" 2.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip whose telephone number is 571-272-4702. The examiner can normally be reached on 7 A.M.- 4:30 P.M. Mon-Thu and every other Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David O. Reip
Primary Examiner
AU 3733